

The Food Traceability Rule requires persons who manufacture, process, pack, or hold foods on the Food Traceability List (FTL) to maintain and provide to their supply chain partners specific information (key data elements or KDEs) for certain critical tracking events (CTEs) in the food’s supply chain. This framework forms the foundation for effective and efficient tracing and clearly communicates the information that FDA needs to perform such tracing.

The information that firms must keep and send forward under the rule varies depending on the type of supply chain activities they perform with respect to an FTL food, from harvesting or production of the food through processing, distribution, and receipt at retail or other point of service. Central to the proposed requirements is the assignment, recording, and sharing of traceability lot codes for FTL foods, as well as linking these lot codes to other information identifying the foods as they move through the supply chain.

Graphics on the subsequent pages provide readers with a list of KDEs required for each CTE performed.



Harvesting

Cooling
(before Initial Packing)

Initial Packing
(RAC)

First Land-Based Receiver

Shipping

Receiving

Transformation

Traceability Plan

Harvesting KDEs (Raw agricultural commodities (RACs) not obtained from a fishing vessel)

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Date of harvesting
- Reference document type and reference document number

Provide to the Initial Packer

- Business name
- Phone number
- Harvesting KDEs (except the reference document type and reference document number)

Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Cooling KDEs (RACs not obtained from a fishing vessel)

- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Commodity and, if applicable, variety of the food
- Quantity and unit of measure of the food
- Location description for where you cooled the food
- Date of cooling
- Location description for the farm where the food was harvested
- Reference document type and reference document number

Provide to the Initial Packer

- Cooling KDEs (except the reference document type and reference document number)



Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel)

KDEs must be linked to the traceability lot you assign for the food that you pack

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the farm where the food was harvested
- For produce:
 - Name of the field or other growing area from which the food was harvested (must correspond to the name used by the grower), or
 - Other information identifying the harvest location at least as precisely as field or growing area name
- For aquacultured food:
 - Name of the container (e.g., pond, pool, tank, cage) from which the food was harvested (must correspond to the container name used by the aquaculture farmer), or
 - Other information identifying the harvest location at least as precisely as the container name
- Business name and phone number for the harvester of the food
- Date of harvesting
- Location description for where the food was cooled (if applicable)
- Date of cooling (if applicable)
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., traceability lot code source), and (if applicable), the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number

Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Initial Packing KDEs (Sprouts)

KDEs must be linked to the traceability lot for the food

All KDEs on previous slide **AND**:

- Location description for the grower of seeds for sprouting and date of seed harvesting, if either is available
- Location description for the seed conditioner or processor, associated seed lot code, and date of conditioning or processing
- Location description for the seed packinghouse (including any repackers), date of packing (and repacking, if applicable), and any associated seed lot code assigned by the seed packinghouse
- Location description for the seed supplier, any seed lot code assigned by the seed supplier (including master lot and sub-lot codes), and any new seed lot code assigned by the sprouter
- Description of the seeds, including seed type or taxonomic name, growing specifications, type of packaging, and (if applicable) antimicrobial treatment
- Date of receipt of the seeds by the sprouter
- Reference document type and reference document number



Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Initial Packing KDEs of RACs (other than a food obtained from a fishing vessel)

For food you receive from a person who is exempt from the rule

KDEs must be linked to the traceability lot for the food

- Commodity and, if applicable, variety of the food received
- Date you received the food
- Quantity and unit of measure of the food received
- Location description for the person from whom you received the food
- Traceability lot code you assigned
- Product description of the packed food
- Quantity and unit of measure of the packed food
- Location description for where you initially packed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference
- Date of initial packing
- Reference document type and reference document number



Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

First Land-Based Receiver KDEs (food obtained from a fishing vessel)

KDEs must be linked to the traceability lot for the food

- Traceability lot code you assigned
- Species and/or acceptable market name for unpackaged food, or the product description for packaged food
- Quantity and unit of measure of the food
- Harvest date range and locations for the trip during which the food was caught
- Location description for the first land-based receiver (i.e., traceability lot code source), and (if applicable) traceability lot code source reference
- Date the food was landed
- Reference document type and reference document number



Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

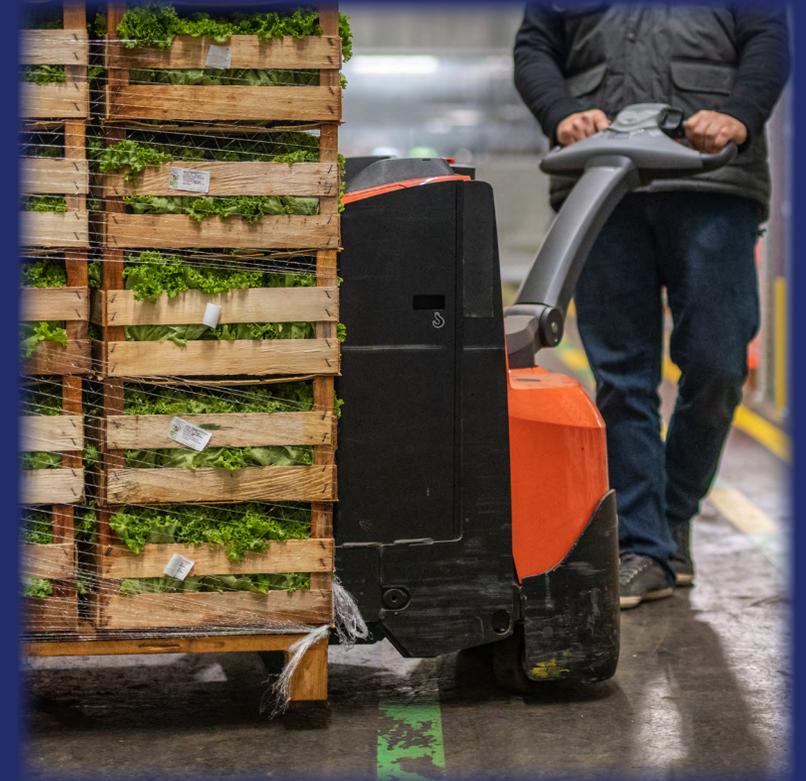
Traceability
Plan

Shipping KDEs (maintain and provide)

KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate subsequent recipient (other than a transporter) of the food
- Location description for the location from which you shipped the food
- Date you shipped the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number (maintain only)

*This section does not apply to the shipment of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel).



Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Receiving KDEs

KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received
- Date you received the food
- Location description for the traceability lot code source or the traceability lot code source reference
- Reference document type and reference document number

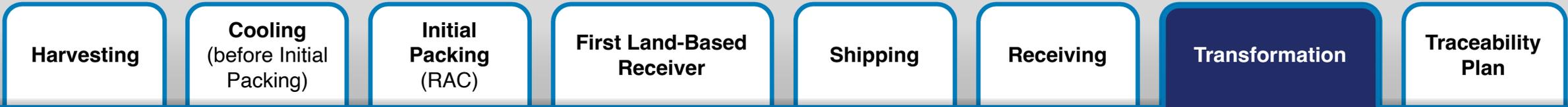
Receiving KDEs

For food you receive from a person who is exempt from the rule

KDEs must be linked to the traceability lot for the food

- Traceability lot code for the food, which you must assign if one has not already been assigned (does not apply to RFEs or restaurants)
- Quantity and unit of measure of the food
- Product description for the food
- Location description for the immediate previous source (other than a transporter) for the food
- Location description for where the food was received (i.e, traceability lot code source) and (if applicable) traceability lot code source reference
- Date you received the food
- Reference document type and reference document number

*This section does not apply to receipt of a food that occurs before the food is initially packed (if the food is a raw agricultural commodity not obtained from a fishing vessel) or to the receipt of a food by the first land-based receiver (if the food is obtained from a fishing vessel).



Transformation KDEs

FTL food(s) used as ingredient(s)

KDEs must be linked to the new traceability lot for the food

- Traceability lot code for the food
- Product description for the food to which the traceability lot code applies
- For each traceability lot used, the quantity and unit of measure of the food used from that lot

Transformation KDEs

New food produced

KDEs must be linked to the new traceability lot for the food

- New traceability lot code for the food
- Location description for where you transformed the food (i.e., the traceability lot code source), and (if applicable) the traceability lot code source reference
- Date transformation was completed
- Product description for the food
- Quantity and unit of measure of the food
- Reference document type and reference document number

For RACs (other than a food obtained from a fishing vessel) that were not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c).

For sprouts that were not initially packed prior to your transformation of the food, you must maintain records containing the information specified in § 1.1330(a) or (c), and also § 1.1330(b).

*This section does not apply to retail food establishments and restaurants with respect to foods they do not ship (e.g., foods they sell or send directly to consumers).

Harvesting

Cooling
(before Initial
Packing)

Initial
Packing
(RAC)

First Land-Based
Receiver

Shipping

Receiving

Transformation

Traceability
Plan

Traceability Plan

Required for all persons covered by the rule

- Description of the procedures you use to maintain the required records, including the format and location of the records
- Description of the procedures you use to identify foods on the FTL that you manufacture, process, pack or hold
- Description of how you assign traceability lot codes to foods on the FTL, if applicable
- Statement identifying a point of contact for questions regarding your traceability plan and records
- If you grow or raise a food on the FTL (other than eggs), a farm map showing the areas in which you grow or raise such foods
 - The farm map must show the location and name of each field (or other growing area) in which you grow a food on the FTL, including geographic coordinates and any other information needed to identify the location of each field or growing area
 - For aquaculture farms, the farm map must show the location and name of each container (e.g., pond, pool, tank, cage) in which you raise seafood on the FTL, including the geographic coordinates and any other information needed to identify the location of each container
- You must update your traceability plan as needed to ensure that the information reflects your current practices and to ensure you are in compliance with the rule
- You must retain your previous traceability plan for 2 years after you update the plan

